

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

STUART A. IRVINE, Individually and as
Executor of the Estate of
MARIE A. IRVINE (Deceased), }
Plaintiffs, }
v. }
JOHNSON & JOHNSON, and JOHNSON &
JOHNSON CONSUMER INC., }
Defendants. }

}

COMPLAINT

JURY TRIAL DEMANDED

I. COMPLAINT

Plaintiff Stuart A. Irvine, Individually and as Executor of the Estate of Marie A. Irvine (Deceased), by and through undersigned counsel, brings this action against Defendants Johnson & Johnson ("J&J") and be Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc. ("Johnson & Johnson Consumer Companies, Inc.") as follows:

II. INTRODUCTION

1. This action arises out of Decedent Marie A. Irvine's diagnosis of ovarian cancer which was directly and proximately caused by her regular and prolonged exposure to talcum powder contained in Defendants' Johnson & Johnson Baby Powder (hereinafter "J&J Baby Powder") and Shower to Shower. Plaintiff brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendants' and/or their corporate predecessors' negligent, willful and wrongful conduct in connection with the design, development, manufacture, testing, packaging,

promoting, advertising, marketing, distribution, labeling, and/or sale of the products known as J&J Baby Powder and Shower to Shower (hereinafter collectively referred to as "Products").

III. PARTIES

2. Decedent Marie A. Irvine was born in 1937 and used J&J Baby Powder and Shower to Shower, the "Products," for nearly her entire life. As a direct and proximate result of using the Products, Decedent was diagnosed with ovarian cancer by pathology on June 28, 1993 following an EUA, cystoscopy, proctoscopy, fractional D&C, drainage of ascites, total abdominal hysterectomy, bilateral salpingo-oophorectomy, tumor debulking, and omentectomy. Decedent expired on February 20, 1994 as a consequence of her metastatic ovarian cancer. Decedent resided at 6 Revere Drive at the time of her diagnosis and death.

3. Plaintiff Stuart A. Irvine is the surviving spouse of Decedent and is the Executor of Decedent's Estate, having been granted full Letters of Administration on May 18, 1994. A copy of the appointment paperwork is attached as **Exhibit A**.

4. Defendant, Johnson & Johnson Consumer Inc. ("Johnson & Johnson Consumer Companies, Inc.") is a New Jersey corporation with its principal place of business in the State of New Jersey.

5. At all pertinent times, Johnson & Johnson was engaged in the business of manufacturing, marketing, testing, promoting, advertising, selling, and/or distributing the Products. At all pertinent times, Johnson & Johnson regularly transacted, solicited, and conducted business in all States of the United States, including the State of New York.

6. Defendant, Johnson & Johnson Consumer Inc. is a New Jersey corporation with its principal place of business in the State of New Jersey.

7. At all pertinent times, Johnson & Johnson Consumer Inc. was engaged in the business of manufacturing, marketing, testing, promoting, advertising, selling, and/or distributing the Products. At all pertinent times, Johnson & Johnson regularly transacted, solicited, and conducted business in all States of the United States, including the State of New York.

8. At all pertinent times, all Defendants were engaged in the research, development, manufacture, design, testing, sale, advertising, and marketing of the Products, and introduced such products into interstate commerce with knowledge and intent that such products be sold in the State of New York.

IV. JURISDICTION AND VENUE

9. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d) because complete diversity exists between Plaintiffs and Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum of value of \$75,000.

10. This Court has personal jurisdiction over Defendants because Defendants are authorized to conduct and do conduct business in the State of New York. Defendants have marketed, promoted, distributed, advertised, and sold the Products in the State of New York and Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through their promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1331(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants transact substantial business in this District.

12. Plaintiff's case may be subject to transfer to the Johnson & Johnson Talcum Powder Marketing, Sales Practices and Products Liability litigation, in the United States District Court for the District of New Jersey, 3:16-md-02738-FLW-LHG, MDL 2738. Plaintiff does not waive any jurisdictional rights including, but not limited to, those recognized in *Lexecon, Inc. v. Milberg, Weiss, Bershad, Hynes & Lerach*, 523 US 26 (1998).

V. FACTS COMMON TO ALL COUNTS

A. Background: Talc as a Carcinogen and Defendant's Knowledge

13. Talc is a magnesium trisilicate and is mined from the earth. Talc is an inorganic mineral.

14. Talc is the main substance in talcum powders. The Johnson & Johnson Defendants manufactured the Products. The Products are composed almost entirely of talc.

15. At all pertinent times, a feasible alternative to the Products has existed. For example, cornstarch is an organic carbohydrate that is quickly broken down by the body with no known health effects. Cornstarch powders have been sold and marketed for the same uses as the Products with nearly the same effectiveness.

16. Historically, "Johnson's Baby Powder" has been promoted as a symbol of freshness, cleanliness, and purity. During the time in question, the Johnson & Johnson

Defendants advertised and marketed this product as the beacon of "freshness" and "comfort", eliminating friction on the skin, absorbing "excess wetness" helping keep skin feeling dry and comfortable, and "clinically proven gentle and mild." The Johnson & Johnson Defendants instructed women through advertisements to dust themselves with this product to mask odors. The bottle of "Johnson's Baby Powder" specifically targets women by stating, "For you, use every day to help feel soft, fresh, and comfortable."

17. During the time in question, the Johnson & Johnson Defendants advertised and marketed the product "Shower to Shower" as safe for use by women as evidenced in its slogan "A sprinkle a day keeps odor away", and through advertisements such as "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel dry, fresh and comfortable throughout the day." And "SHOWER to SHOWER can be used all over your body."

18. In 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by Dr. W.J. Henderson and others in Cardiff, Wales.

19. In 1982, the first epidemiologic study was performed on talc powder use in the female genital area. This study was conducted by Dr. Daniel Cramer and others. This study found a 92% increased risk in ovarian cancer with women who reported genital talc use. Shortly after this study was published, Dr. Bruce Semple of Johnson & Johnson came and visited Dr. Cramer about his study. Dr. Cramer advised Dr. Semple that Johnson & Johnson should place a warning on its talcum powders about the ovarian cancer risks so that women can make an informed decision about their health.

20. Since 1982, there have been approximately twenty-two (22) additional epidemiologic studies providing data regarding the association of talc and ovarian cancer. Nearly all of these studies have reported an elevated risk for ovarian cancer associated with genital talc use in women.

a. In 1983, a case-control study found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area. Hartge, P., *et al.* Talc and Ovarian Cancer. *JAMA*. 1983; 250(14):1844.

b. In 1988, a case control study of 188 women diagnosed with epithelial ovarian cancer and 539 control women found that 52% of the cancer patients habitually used talcum powder on the genital area before their cancer diagnosis. The study showed a 50% increase in risk of ovarian cancer in women that used talcum powder on their genital area and a positive dose-response relationship. Whittemore AS, *et al.* Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am.J. Epidemiol.* 1988 Dec; 128(6):1228-40.

c. A 1989 study looked at 235 women diagnosed with epithelial ovarian cancer and 451 controls, and found a 29% increased risk in ovarian cancer with women who reported genital talcum powder use more than once each week. Booth, M., *et al.* Risk factors for ovarian cancer: a case-control study. *Br J Cancer*. 1989 Oct; 60(4):592-8.

d. In 1992, a case-control study found a statistically significant 80% increased risk of ovarian cancer in women with more than 10,000 lifetime perineal applications of talc, demonstrating a positive dose-response relationship. Harlow BL, *et*

a. Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol.* 1992 Jul; 80(1):19-26.

e. Another 1992 case-control study reported a 70% increased risk from genital talc use and a 379% increased risk of ovarian cancer of women who used talc on sanitary napkins in their genital area. Rosenblatt, K.A. et al. Mineral fiber exposure and the development of ovarian cancer. *Gynecol Oncol.* 1992 Apr; 45(1):20-5.

f. In 1995, the largest study of its kind to date found a statistically significant 27% increased risk in ovarian cancer for women who regularly use talc in the abdominal or perineal area. Purdie, D., et al. Reproductive and other factors and risk of epithelial ovarian cancer: An Australian case-control study. Survey of Women's Health Study Group. *Int J Cancer.* 1995 Sep 15; 62(6):678-84.

g. In 1996, a case-control study found a statistically significant 97% increased risk of ovarian cancer in women who used what they described as a "moderate" or higher use of talc-based powders in their genital area. See Shushan, A., et al. Human menopausal gonadotropin and the risk of epithelial ovarian cancer. *Fertil. Steril.* 1996 Jan; 65(1):13-8.

h. In 1997, a case control study of 313 women with ovarian cancer and 422 without this disease found that the women with cancer were more likely to have applied talcum powder to their external genitalia area. Women using these products had a statistically significant 50% to 90% higher risk of developing ovarian cancer. Cook, LS, et al. Perineal powder exposure and the risk of ovarian cancer. *Am. J Epidemiol.* 1997 Mar 1; 145(5):459-65.

i. In 1997, a case-control study involving over 1,000 women found a statistically significant increased risk of 42% for ovarian cancer for women who applied talc via sanitary napkins to their perineal area. Chang, S, et al. Perineal talc exposure and risk of ovarian carcinoma. *Cancer.* 1997 Jun 15; 79(12):2396-401.

j. In 1998, a case-control study found a 149% increased risk of ovarian cancer in women who used talc-based powders on their perineal area. Godard, B., et al. Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study. *Am J Obstet Gynecol.* 1998 Aug; 179(2):403-10.

k. Dr. Daniel Cramer conducted another case-control study in 1999, observing 563 women newly diagnosed with epithelial ovarian cancer and 523 women in a control. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineal area and an 80% increase in risk for women with over 10,000 lifetime applications. Cramer, DW, et al. Genital talc exposure and risk of ovarian cancer. *Int J Cancer.* 1999 May 5; 81(3):351-56.

l. In 2000, a case-control study of over 2,000 women found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. Ness, RB, et al. Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology.* 2000 Mar; 11(2):111-7.

m. In 2004, a case-control study of nearly, 1,400 women from 22 counties in Central California found a statistically significant 37% increased risk of epithelial ovarian cancer from women's genital talc use, and a 77% increased risk of serous invasive ovarian cancer from women's genital talc use. Importantly, this study

also examined at women's use of cornstarch powders as an alternative to talc, and found no increased risk in ovarian cancer in women in the cornstarch group, further supporting the causal connection between genital talc use and ovarian cancer. Mills, PK, et al. Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int J Cancer.* 2004 Nov 10; 112(3):458-64.

n. In 2008, a combined study of over 3,000 women from a New England-based case-control study found a general 36% statistically significant increased risk of epithelial ovarian cancer from genital talc use and a 60% increased risk of the serous invasive ovarian cancer subtype. The study also found a strong dose-response relationship between the cumulative talc exposure and incidence of ovarian cancer, adding further support to the causal relationship. Gates, MA, et al. Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer. *Cancer Epidemiol Biomarkers Prev.* 2008 Sep; 17(9):2436-44

o. A 2009 case-control study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use, with an overall statistically significant 53% increased risk of ovarian cancer from genital talc use. That increased risk rose dramatically, to 108%, in women with the longest duration and most frequent talc use. Wu, AH, et al. Markers of inflammation and risk of ovarian cancer in Los Angeles County. *Int. J Cancer.* 2009 Mar 15; 124(6):1409-15.

p. In 2011, another case-control study of over 2,000 women found a 27% increased risk of ovarian cancer from genital talc use. Rosenblatt, KA, et al.

Genital powder exposure and the risk epithelial ovarian cancer. *Cancer Causes Control.* 2011 May; 22(5):737-42.

q. In June of 2013, a pooled analysis of over 18,000 women in eight case-control studies found a 20% to 30% increased risk of women developing epithelial ovarian cancer from genital powder use. The study concluded by stating, "Because there are few modifiable risk factors for ovarian cancer, avoidance of genital powders may be a possible strategy to reduce ovarian cancer incidence." Terry, KL, et al. Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prev Res (Phila).* 2013 Aug; 6(8):811-21.

21. Researchers have also examined the link between endometrial cancer, a form of uterine cancer, and application of talcum powder to the perineal area.

22. In 2010, one such study analyzed data from a 1976 cohort study of over 66,000 women, and found a statistically significant 21% increased risk of endometrial (uterine) cancer in postmenopausal women who had ever applied talcum powder in the perineal area. This risk rose to 24% for postmenopausal women who applied talc in the perineal area "regularly," defined as at least once a week. Karageorgi S., et al. (2010) Perineal use of talcum powder and endometrial cancer risk. *Cancer Epidemiol Biomarkers Prev.* 2010 May; 19:1269-1275.

23. In 1993, the United States National Toxicology Program published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity. Talc was found to be a carcinogen, with or without the presence of asbestos-like fibers.

24. In response to the United States National Toxicology Program's study, the Cosmetic Toiletry and Fragrance Association (CTFA) formed the Talc Interested Party

Task Force (TIPTF). Johnson & Johnson, Inc., and Johnson & Johnson Consumer Companies, Inc. were members of the CFTA. The stated purpose of the TIPTF was to pool financial resources of these companies in an effort to collectively defend talc use at all costs and to prevent regulation of any type over this industry. The TIPTF hired scientists to perform biased research regarding the safety of talc, members of the TIPTF edited scientific reports of the scientists hired by this group prior to the submission of these scientific reports to governmental agencies, members of the TIPTF knowingly released false information about the safety of talc to the consuming public, and used political and economic influence on regulatory bodies regarding talc. All of these activities have been well coordinated and planned by these companies and organizations over the past four (4) decades in an effort to prevent regulation of talc and to create confusion to the consuming public about the true hazards of talc relative to cancer.

25. On November 10, 1994, the Cancer Prevention Coalition mailed a letter to then Johnson & Johnson C.E.O, Ralph Larson, informing his company that studies as far back as 1960's ". . . show[] conclusively that the frequent use of talcum powder in the genital area pose[] a serious health risk of ovarian cancer." The letter cited a recent study by Dr. Bernard Harlow from Harvard Medical School confirming this fact and quoted a portion of the study where Dr. Harlow and his colleagues discouraged the use of talc in the female genital area. The letter further stated that 14,000 women per year die from ovarian cancer and that this type of cancer is very difficult to detect and has a low survival rate. The letter concluded by requesting that Johnson & Johnson withdraw talc products from the market because of the alternative of cornstarch powders, or at a

minimum, place warning information on its talc-based boy powders about ovarian cancer risk they pose.

26. In 1996, the condom industry stopped dusting condoms with talc due to the growing health concerns.

27. In February of 2006, the International Association for the Research of Cancer (IARC) part of the World Health Organization published a paper whereby they classified perineal use of talc based body powder as a "Group 2B" human carcinogen. IARC which is universally accepted as the international authority on cancer issues, concluded that studies from around the world consistently found an increased risk of ovarian cancer in women from perineal use of talc. IARC found that between 16-52% of women in the world were using talc to dust their perineum and found an increased risk of ovarian cancer in women talc users ranging from 30-60%. IARC concluded with this "Evaluation": "There is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder." By definition "Limited evidence of carcinogenicity" means "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."

28. In approximately 2006, the Canadian government under The Hazardous Products Act and associated Controlled Products Regulations classified talc as a "D2A," "very toxic," 51 "cancer causing" substance under its Workplace Hazardous Materials Information System (WHMIS). Asbestos is also classified as "D2A".

29. In 2006, Imerys Talc began placing a warning on the Material Safety Data Sheets (MSDS) it provided to the Johnson & Johnson Defendants regarding the talc it sold to them to be used in the Products. These MSDSs not only provided the warning information about the IARC classification but also included warning information regarding "States Rights to Know" and warning information about the Canadian Government's "D2A" classification of talc as well.

30. Defendants had a duty to know and warn about the hazards associated with the use of the Products.

31. Defendants failed to inform customers and end users including the Decedent of the Products known catastrophic health hazard associated with the use of the Products.

32. In addition, Defendants procured and disseminated false, misleading, and biased information regarding the safety of the Products to the public including the Decedent and used influence over governmental and regulatory bodies regarding talc.

B. Decedent's Use of the Products

33. Decedent was born in 1937 and was a resident of Huntington, New York.

34. When Decedent was an infant, her mother applied Shower to Shower, and J&J Baby Powder to her. As she grew up, and throughout her life, Decedent continued to use the Products daily.

35. Decedent continued to use the Products following her initial diagnosis of ovarian cancer in 1993.

36. There was never any indication, on the Products, packaging or otherwise, that this normal use could and would cause Decedent to have developed or to develop ovarian cancer.

37. Decedent was diagnosed with ovarian cancer on June 28, 1993.

38. Decedent underwent chemotherapy and surgery, including her EUA, cystoscopy, proctoscopy, fractional D&C, drainage of ascites, total abdominal hysterectomy, bilateral salpingo-oophorectomy, tumor debulking, and omentectomy.

39. Decedent's ovarian cancer was the cause of her death on June 28, 1993.

**COUNT ONE – STRICT LIABILITY
(FAILURE TO WARN)**

40. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

41. At all pertinent times, the Johnson & Johnson Defendants were manufacturing, marketing, testing, promoting, selling and/or distributing the Products in the regular course of business.

42. At all pertinent times, Decedent used the Products to powder her perineal area, which is a reasonably foreseeable use.

43. At all pertinent times, Defendants in this action knew or should have known that the use of talcum powder based products in the perineal area significantly increases the risk of cancer, including, but not limited to, ovarian and uterine cancer, based upon scientific knowledge dating back for decades.

44. At all pertinent times, including the time of sale and consumption, the Products when put to the aforementioned reasonably foreseeable use, were in an unreasonably dangerous and defective condition because they failed to contain

adequate and proper warnings and/or instructions regarding the increased risk of cancer, including, but not limited to, ovarian and uterine cancer, associated with the use of the Products by women to powder their perineal area. Defendants themselves failed to properly and adequately warn and instruct Decedent as to the risks and benefits of the Products given her need for this information.

45. Had Decedent received a warning that the use of the Products would significantly increase her risk of developing cancer, she would not have used them. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of the Products, Decedent was injured catastrophically, and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic damages and, ultimately, death.

46. The development of ovarian cancer by Decedent was the direct and proximate result of the unreasonably dangerous and defective condition of the Products at the time of sale and consumption, including their lack of warnings; Decedent suffered injuries and damages including, but not limited to, physical and mental pain and suffering, fear of death, medical expenses and, ultimately, death.

47. Defendants' products were defective because they failed to contain warnings and/or instructions, and breached express warranties and/or failed to conform to express factual representations upon which Decedent justifiably relied in electing to use the Products. The defect or defects made the Products unreasonably dangerous to persons, such as Decedent, who could reasonably be expected to use and rely upon such products. As a result, the defect or defects were a producing cause of Decedent's injuries and damages.

48. Defendants' products failed to contain, and continue to this day not to contain, adequate warnings and/or instructions regarding the increased risk of cancer, including, but not limited to, ovarian and uterine cancer, with the use of their products by women. Defendants continue to market, advertise, and expressly represent to the general public that it is safe for women to use their products regardless of application. Defendants continue with these marketing and advertising campaigns despite having scientific knowledge that dates back to the 1960's that their products increase the risk of cancer in women when used in the perineal area.

49. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life.

**COUNT TWO – STRICT LIABILITY
(DESIGN AND/OR MANUFACTURING DEFECT)**

50. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

51. Defendants engaged in the design, development, manufacture, marketing, sale, and distribution of the Products in a defective and unreasonably dangerous condition to consumers, including Decedent.

52. Defendants caused the Products to enter the stream of commerce and to be sold through various retailers, where Decedent purchased the Products.

53. The Products were expected to, and did, reach consumers, including Decedent, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

54. Decedent used the Products in a manner normally intended, recommended, promoted, and marketed by Defendants.

55. Products failed to perform safely when used by Decedent in a reasonably foreseeable manner, specifically increasing her of developing ovarian cancer.

56. The propensity of talc fibers to translocate into the female reproductive system, including, but not limited to, the ovaries and endometrial lining of the uterus, thereby substantially increasing risk of cancer, including, but not limited to, ovarian and uterine cancer, renders the Products unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer, including the Decedent.

57. Importantly, the Products are an inessential cosmetic product that do not treat or cure any serious disease. Further, safer alternatives, including corn-starch based powders, have been readily available for decades.

58. Defendants have known, or should have known, that the Products are unreasonably dangerous when used by a woman in her perineal area but have continued to design, manufacture, sell, distribute, market, promote, and supply the Products so as to maximize sales and profits at the expense of public health and safety in conscious disregard of the foreseeable harm to the consuming public, including Decedent.

59. As a direct and proximate result of Defendants' conduct, including actions, omissions, and misrepresentations, Decedent sustained the following damages:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

COUNT THREE – NEGLIGENCE

60. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

61. The Johnson & Johnson Defendants were negligent in marketing, designing, manufacturing, producing, supplying, inspecting, testing, advertising selling and/or distributing the Products in one or more of the following respects:

- In failing to warn Decedent and the general public of the hazards associated with the use of Products;
- In failing to properly test their products to determine adequacy and effectiveness or safety measures, if any, prior to releasing the Products for consumer use;
- In failing to properly test their products to determine the increased risk of ovarian cancer during the normal and/or intended use of the Products;
- In failing to inform ultimate users, including the Decedent, as to the safe and proper methods of handling and using the Products;

- In failing to remove the Products from the market when Defendants knew or should have known the Products were defective;
- In failing to instruct the ultimate users, including the Decedent, as to the methods for reducing the type of exposure to the Products which caused increased risk of cancer, including, but not limited to, ovarian and uterine cancer and resulting death;
- In failing to inform the public in general and Decedent in particular of the known dangers of using the Products for dusting the perineum;
- In failing to advise users including the Decedent how to prevent or reduce exposure that caused increased risk for cancer, including, but not limited to, ovarian and uterine cancer;
- In marketing and labeling the Products as safe for all uses despite knowledge to the contrary; and
- In failing to act like a reasonably prudent company under similar circumstances.

Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Decedent.

62. At all pertinent times, the Johnson & Johnson Defendants knew or should have known that the Products were unreasonably dangerous and defective when put to their reasonably anticipated use.

63. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, and loss of enjoyment, impairment of quality of life and, ultimately, death.

COUNT FOUR – BREACH OF EXPRESS WARRANTY

64. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

65. The Johnson & Johnson Defendants expressly warranted, through direct-to-consumer marketing, advertisements, and labels, including to the Decedent that the Products were safe and effective for reasonably anticipated uses, including use by women in the perineal area.

66. The Products did not conform to these express representations because they cause serious injury when used by women in the perineal area in the form of cancer, including, but no limited to, ovarian and uterine cancer.

67. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

COUNT FIVE – BREACH OF IMPLIED WARRANTIES

68. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

69. At the time the Defendants manufactured, marketed, labeled, promoted, distributed and/or sold the Products, the Johnson & Johnson Defendants knew of the uses for which the Products were intended, including use by women in the perineal area, and impliedly warranted the Products to be of merchantable quality and safe for such use.

70. Defendants breached their implied warranties of the Products sold to Decedent because they were not fit for their common, ordinary and intended uses, including use by women in the perineal area.

71. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

COUNT SIX – PUNITIVE DAMAGES

72. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

73. Defendants have acted willfully, wantonly, with an evil motive, and recklessly in one or more of the following ways:

- a. Defendants knew of the unreasonably high risk of cancer, including, but not limited to, ovarian and uterine cancer, posed by the Products before manufacturing, marketing, distributing and/or selling the Products, yet purposefully proceeded with such action;
- b. Despite their knowledge of the high risk of cancer, including, but not limited to, ovarian and uterine cancer, associated with the Products, Defendants affirmatively minimized this risk through marketing and promotional efforts and product labeling;
- c. Through the actions outlined above, Defendants expressed a reckless indifference to the safety of users of the Products, including Decedent. Defendants' conduct, as described herein, knowing the dangers and risks of the Products, yet concealing and/or omitting this information, in furtherance of their conspiracy and concerted action was outrageous because of Defendants' evil motive or reckless indifference to the safety of users of the Products.

74. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and /or omissions:

- a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

COUNT SEVEN – NEGLIGENT MISREPRESENTATION

75. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

76. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Decedent, and the public, that the Products had been tested and found to be safe and effective for use in the perineal area. The representations made by Defendants, in fact, were false.

77. Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Products' high risk of unreasonable, dangerous, adverse side effects.

78. Defendants breached their duty in representing that the Products have no serious side effects.

79. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, but not limited to, ovarian and uterine cancer.

80. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

COUNT EIGHT – FRAUDULENT CONCEALMENT

81. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

82. Defendants owed consumers, including Decedent, a duty to fully and accurately disclose all materials facts regarding the Products, not to conceal material defects related thereto, not to place these defective products into the stream of commerce, and to fully and accurately label product packaging. To the contrary, Defendants explicitly and/or implicitly represented that the Products were safe and effective.

83. Defendants actively and intentionally concealed and/or suppressed material facts, in whole or in part, to induce consumers, including Decedent, to purchase and use the Products and did so at her expense. Specifically:

a. Defendants have been aware of the positive association between feminine talc use and cancer demonstrated by epidemiology studies since at least 1982 and more than a dozen such published studies, including meta-analyses, have been published demonstrating similar results;

b. Defendants have been aware, for decades, of the propensity for talc particles to translocate from the perineum through the vaginal tract into the ovaries;

c. IARC, the recognized world authority of agent carcinogenicity, has determined that there is a credible causal between feminine talc use and ovarian cancer;

d. Johnson & Johnson's own paid consultant, Dr. Alfred Wehner, advised the company on multiple occasions, by at least 1997, that Johnson & Johnson's denial of a positive association between feminine talc use and ovarian cancer was "technically and factually incorrect."; and

e. Recent studies have again confirmed a statistically significant correlation between talcum powder use in the perineal area and uterine cancer.

84. Defendants made the misrepresentation and/or omissions for the purpose of deceiving and defrauding Decedent and with the intention of having her act and rely on such misrepresentations and/or omissions.

85. Defendants knew that their concealments, misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive, and deceitful when they were made. Alternatively, Defendants concealed information, and/or made the representations with such reckless disregard for the truth that knowledge of the falsity can be imputed to them.

86. Defendants profited, significantly, from their unethical and illegal conduct that caused Decedent to purchase and habitually use a dangerous and defective product.

87. Defendants' actions, and Decedent's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

88. Decedent sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

**COUNT NINE – FRAUD
(INTENTIONAL MISREPRESENTATION)**

89. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

90. Defendants, who engaged in the development, manufacture, marketing, sale and distribution of personal hygiene products, including the Products, owed a duty to provide accurate and complete information regarding said products.

91. Defendants fraudulently misrepresented the use of the Products as safe and effective, including to Decedent, specifically:

a. Johnson & Johnson's website calls it a "misconception" that talc is baby powder can be "absorbed into the body";

b. Johnson & Johnson print advertisements directed at adult women asserted that, because Johnson & Johnson Baby Powder is used on babies, women can "trust" that Johnson & Johnson will take "just as much care" of their skin;

c. Misleading consumers in advertisements that the talc in Johnson & Johnson Baby Powder is safe because it comes from "nature" and is "pure";

d. Johnson & Johnson, on its website, claims that "30 years of research by independent scientists, review boards and global authorities" have concluded that talc can be used safely in personal care products," failing to mention the dozens of studies demonstrating a relationship between feminine talc use and ovarian cancer, as well as the decision by IARC to label feminine talc powder use as "possibly carcinogenic"; and

e. On the Johnson & Johnson Baby Powder bottle, Defendants include a conspicuous warning to mothers to prevent babies from inhaling the powder and the inclusion of this lone warning implies to the consumer that Johnson & Johnson Baby Powder is safe in all other manners of use.

92. Defendants knew that these misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive and deceitful when they were made.

93. Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding consumers, including Decedent, with the intention of having them act and rely on such misrepresentations and/or omissions.

94. Decedent relied, with reasonable justification, on the misrepresentations by Defendants, which induced her to purchase and use the Products on a regular basis for decades.

95. Defendants profited, significantly, from their unethical and illegal conduct that fraudulently induced Decedent, and millions of other consumers, to purchase a dangerous and defective product.

96. Defendants' actions, and Decedent's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

97. As a foreseeable, direct, and proximate result of the aforementioned fraudulent misrepresentations by Defendants, Decedent sustained the following damages:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

**COUNT TEN – CONSUMER FRAUD
(VIOLATION OF NY GBL §§ 349 AND 350)**

98. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

99. New York's UCL prohibits any "[d]eceptive acts or practices in the conduct of any business, trade or commerce . . ." GBL § 349. Defendants' misrepresentations and omissions described herein are "deceptive acts or practices" under New York law.

100. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including the Decedent herein and his physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Defendants' Products.

101. Decedent purchased and used the Johnson & Johnson Defendants' Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of GBL §§ 349 and 350.

102. Had Defendants not engaged in the deceptive conduct described herein, Decedent would not have purchased and/or paid for Defendants' Products, and would not have incurred related injuries and damages.

103. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monetary gain from Decedent for the Products that would not have been paid had Defendants not engaged in fraudulent conduct.

104. Defendants engaged in fraudulent methods of competition and deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent conduct that creates a likelihood of confusion or misunderstanding.

105. Defendants intended for the public including the Decedent, Decedent's physicians and medical providers, to rely on their representations and advertisements regarding the Products in order to achieve monetary gain from Decedent through her purchase of the Products.

106. Decedent was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at

Decedent and other consumers was to create demand for and sell the Products. Each aspect of Defendants' conduct combined to artificially create sales of the Products.

107. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Products.

108. Had Defendants not engaged in the deceptive conduct described above, Decedent would not have purchased and/or paid for the product, and would not have incurred related injuries and damages.

109. Defendants' intentional, deceptive, unconscionable, and fraudulent representations and material omissions to the public, Decedent, physicians, and consumers, constituted unfair and deceptive acts and trade practices in violation of GBL §§ 349 and 350.

110. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of GBL §§ 349 and 350.

111. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices, or have made false representations in violation of GBL §§ 349 and 350.

112. Defendants are the suppliers, manufacturers, advertisers, and sellers of the Products, and are subject to liability under GBL §§ 349 and 350 for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

113. Defendants violated GBL §§ 349 and 350, by knowingly and falsely representing that Defendants' Products were fit to be used for the purpose for which

they were intended, when in fact the Products were and are defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

114. Defendants had actual knowledge of the defective and dangerous condition of Defendants' Products, and failed to take any action to cure such defective and dangerous conditions.

115. Decedent reasonably relied upon Defendants' misrepresentations and omissions in determining which Products to use.

116. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to Decedent and other consumers constituted deceptive acts and practices.

117. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Decedent suffered ascertainable losses and damages.

118. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350, Decedent sustained the following damages:

a. Economic losses including medical care, lost earnings, funeral, burial and related expenses.

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, fear of death, inconvenience, loss of enjoyment, impairment of quality of life and, ultimately, death.

COUNT ELEVEN – RESTITUTION OR DISGORGMENT BASED ON UNJUST ENRICHMENT

119. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

120. As a result of the Johnson & Johnson Defendants' unlawful, fraudulent and misleading labeling, advertising, marketing and sales of the Products described herein, Defendants were unjustly enriched at the expense of Decedent.

121. Defendants sold their Products to Decedent as described herein, and profited therefrom. It would be against equity and good conscience to permit Defendants to retain the ill-gotten benefits Defendants received from Decedent, in light of the fact that the Products were not what Defendants purported them to be. Thus, it would be unjust and inequitable for Defendants to retain the benefit without restitution or disgorgement to Plaintiff of monies paid to Defendants for the Products.

COUNT TWELVE – WRONGFUL DEATH

122. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

123. As a direct and proximate result of Defendants' failure to provide timely and appropriate warning to the public, physicians, and patients, including Decedent, and as a direct result of the negligence, carelessness, other wrongdoing and actions or omissions of Defendants described herein, Decedent suffered from metastatic ovarian cancer resulting in her death on June 28, 1993.

124. As a direct and proximate cause of the acts or omissions of Defendants described herein, Plaintiff suffered and will continue to suffer mental pain and suffering, and loss of Decedent's society, companionship, comfort and care. Plaintiff may also recover for any medical and/or funeral expenses paid by them due to the injury and resulting death of Decedent.

COUNT THIRTEEN – SURVIVAL ACTION

125. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

126. As a direct and proximate result of the conduct of Defendants, Decedent, prior to their death, was obligated to spend various sums of money to treat their injuries, which debts have been assumed by their Estate. As a direct and proximate cause of the aforesaid, Decedent was caused pain and suffering, mental anguish, and impairment of the enjoyment of life, until the date of their death and, as a direct and proximate result of the aforesaid, Decedent suffered a loss of earnings and earning capacity. Decedent's spouse, as Executor of the Estate, brings this claim on behalf of the Estate for damages under any and all applicable statute or common law.

127. As a direct and proximate result of the conduct of Defendants, Decedent and their spouse, until the time of Decedent's death, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder. This claim is brought on behalf of the Estate of the Decedent pursuant to any and all applicable statutes or common law.

128. As a direct and proximate result of the conduct of Defendants, and including the observances of the suffering of the Decedent, until the date of their death, Plaintiff suffered permanent and ongoing psychological damage.

129. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Decedents until the date of their death, Plaintiff has and will continue to suffer permanent and ongoing

psychological damage which may require future psychological and medical treatment. Decedent's spouse, as Executor of the Estate, brings the claim on behalf of the Estate for damages any and all applicable statutes or common law and in their own right.

130. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of Decedent, Plaintiff and the public.

131. As a result of the Defendants' conduct, the Plaintiff suffered the injuries and damages specified herein.

132. Accordingly, the Plaintiff seeks and is entitled to compensatory and punitive damages in an amount to be determined at trial.

133. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the Products, Plaintiffs demand judgment against the Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, damages for wrongful death, together with interest, costs of suit, attorneys' fees, punitive damages and such further relief as the Court deems equitable and just.

COUNT FOURTEEN – LOSS OF CONSORTIUM

134. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

135. At all relevant times hereto, Decedent had spouse (hereafter referred to as "Spouse Plaintiff") who has suffered injuries and losses as a result of the Products and Decedent's injuries and subsequent death.

136. For the reasons set forth herein, Spouse Plaintiff has necessarily paid and has become liable to pay for medical aid, treatment, monitoring, medications and other expenditures, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

137. For the reasons set forth herein, Spouse Plaintiff has suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

138. Spouse Plaintiff alleges that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

139. Spouse Plaintiff has suffered great emotional pain and mental anguish.

140. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiff has sustained and will continue to sustain severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiff jointly and severally for all general, special and equitable relief to which Spouse Plaintiff is entitled by law.

TOLLING OF STATUTE OF LIMITATIONS

141. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

142. Decedent suffered an illness that had a latency period and did not arise until many years after exposure. Plaintiff was not aware at the time of Decedent's diagnosis that her ovarian cancer was caused by her use of the Defendants' Products. Consequently, the discovery rule applies to this case and the statute of limitations has

been tolled until the day that Plaintiff knew or had reason to know that Decedent's ovarian cancer was linked to her use of Defendants' Products.

143. Furthermore, the running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and conduct. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and Decedent the true risks associated with the Products.

144. As a result of Defendants' actions, Plaintiff, Decedent and Decedent's prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

145. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of the Products. Defendants were under a duty to disclose the true character, quality and nature of the Products because this was non-public information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the public, Decedent's medical providers and/or health facilities.

146. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable product, notwithstanding the known or reasonably known risks. Decedent's medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demands judgment against Defendants on each of the above-referenced claims and causes of action, and as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, emotional distress, fear of death, loss of enjoyment of life, loss of consortium, wrongful death and other non-economic damages in an amount to be determined at trial of this action;
- b. Awarding compensatory damages in excess of \$75,000 for Plaintiff's injuries in an amount to be determined at trial of this action;
- c. Awarding compensatory damages for Plaintiff's loss of love, support and companionship in an amount to be determined at trial of this action.
- d. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings, loss of inheritance, funeral, burial and related expenses and other economic damages in an amount to be determined at trial of his action;
- e. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Decedent in an amount sufficient to punish Defendants and deter future similar conduct;
- f. For an order requiring Defendants to immediately cease and desist from all fraudulent, deceptive, unlawful, and illegal conduct described above;
- g. Pre-judgment interest;
- h. Post-judgment interest;

- i. Awarding Plaintiff reasonable attorneys' fees;
- j. Awarding Plaintiff the costs of these proceedings; and
- k. Such other and further relief as this Court deems just and proper.

Dated:

4/27/2021

By:



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